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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,851	03/20/2000	William Pendergast	36780028US04	6061

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/531,851	PENDERGAST ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-15,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15, 18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Notice of Appeal filed February 24, 2005 and Appeal Brief filed August 4, 2007 are noted by instant Examiner. However, because PROSECUTION IS NOW REOPENED, the noted filings are hereby held in abeyance and applicant is respectfully requested to respond to the new issues raised in the following Office action.

Claims **1-11, 16 and 20-21** have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as per the Appeal Brief filed August 4, 2005. No supplemental Information Disclosure Statements (IDSs) have been filed since the last Office action, but the reference filed with the Appeal Brief is noted and has been made of record on the PTO-892 attached hereto.

Claims **12-15, 17, 18 and 19** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **12-15 and 17-19** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to the administration of an alpha, omega-5', 5"-dinucleotide oligo-phosphate to cause some effect on a cervical or vaginal mucus membrane of a female mammalian host in need thereof wherein the oligo-phosphate chain can range from 2 to 6 in length and wherein the variable group "X" may be O, CH_2, CF_2 or NH. However, inspection of the disclosure at page 20-22 wherein Examples are disclosed reveals that only "uridine triphosphate (UTP)" has been shown by applicant to have the effect claimed in claim **12**. Inspection of the record does not reveal to examiner where applicant has provided any showing that UTP and the compounds defined in claim **12** have either overlapping or equivalent pharmacological activity. Therefore, thus far applicant has failed to provide a written description of how to use the compounds defined in the claims to achieve the claimed result or any other pharmacological result.

Claims **12-15 and 17-19** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for administration of UTP to enhance vaginal and cervical secretions, does not reasonably provide enablement for the instant defined Bis-(5'-uridinyl)oligophosphates as pharmacological equivalents of UTP in this medicinal role. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims are broadly defined to include a very large array of alpha, omega-bis-(5-nucleosidyl)oligophosphates as active ingredients in the treatment of mammalian female hosts in need of enhanced cervical or vaginal mucoid secretions.

B. The nature of the invention: The instant claims are directed to the administration of alpha, omega-bis-(5-nucleosidyl)oligophosphates as active ingredients in the treatment of mammalian female hosts in need of enhanced cervical or vaginal mucoid secretions.

C. The state of the prior art: The prior art discloses some other applications for UTP but does not disclose the instant claimed application as presently claimed for alpha, omega-bis-(5-nucleosidyl)oligophosphates.

D. The level of one of ordinary skill: The instant claims would require one or ordinary skill in the treatment of medicinal conditions of the mammalian female reproductive tract.

E. The level of predictability in the art: In light of the apparent absence of test data concerning the medicinal activity of the instant alpha, omega-bis-(5-nucleosidyl)oligophosphates, the predictability of medicinal activity is deemed to be very low.

F. The amount of direction provided by the inventor: The instant disclosure only teaches the administration of UTP and does not teach the administration of any alpha, omega-bis-(5-nucleosidyl)oligophosphates to treat any disease condition or symptom thereof.

G. The existence of working examples: The instant disclosure's working examples are limited to two and both disclose administration of UTP only, and do not disclose administration of even a single alpha, omega-bis-(5-nucleosidyl)oligophosphates

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the instant disclosure fails to provide sufficient experimental guidance to permit the ordinary practitioner to know whether the instant claimed active ingredients are effective in the treatment of any medical condition including the conditions specified in the instant claims.

Claim **12** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **12** the terms "purine residue" and "pyrimidine residue" are not clearly distinguishable from generic terms for classes of compounds and are also incomplete for failure to define the particular --purinyl-- and --pyrimidinyl-- substituent groups the instant claim is directed to.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **12-15 and 17-19** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-8*** of U. S Patent No. **6,462,028**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about

the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
04/04/2007

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